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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,103	11/12/2003	Douglas Craig Scott	9118M2	5133

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,103	SCOTT ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-17 is/are rejected.
- 7) ☒ Claim(s) 1, 12 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/03/06 has been entered.

Response to remarks

The response filed October 03, 2006 presents remarks and arguments to the office action mailed May 04, 2006. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed 10/03/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of claims

Claims 1, 3, 12-14 and 16 have been amended.

Claims 1-4 and 6-17 are pending.

Claim 5 is cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 1 and 16 are objected to because of the following informalities: line 14 of claim 1 after 10 should be ml and not mils. Appropriate correction is required.

Claims 1,12 and 16 are objected to because of the following informalities: A claim should only contain one period. Appropriate correction is required.

Maintained New Claim Rejections - 35 USC § 112

Applicant argues the term “about” stating the case law gives flexibility to the use of the term.

In response while this is so for the term about, it still does not satisfy the use of the terms or “less than about” or “for at least about”. Careful consideration has been give to Applicants’ argument and the case law has been considered, but the explanation is unpersuasive. The rejection is maintained and again repeated below.

Claims 1-4, 9, 12-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “from about” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control is it from or is it about?.

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Claims 1-2, 12, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. Less than about is interpreted to be less than the amount given and about is interpreted to be any numerical around the range given for example less than about 1 g in claim 1 can be anywhere from 0.000-1g and 1-9 g.

Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The "for at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. For at least about can be interpreted to be \geq , for example for atleast 5 mins is interpreted to be from 1 to 2 and from 2-infinite as in claim 14.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Applicant's arguments have been fully considered but they are not persuasive

(see below):

Applicant traverses: That the Lawlor reference teaches away from the claimed invention (see page 9, para. 4) stating that Lawlor disclosure of an oral dentifrice is retained only for 5-30 seconds and the composition disappears by 5 minutes.

In response, (i) Please note that claim 1 is broad and the insoluble particulate has a solubility less than 1g/30 g at room temperature. The limitations of the claims are clearly met. With regards to the argument that the Lawlor reference does not teach the composition remaining in the oral cavity more than 5 minutes is unpersuasive, clearly because the claims are directed to a composition, having it retained in the oral cavity is a characteristic and does not have a patentable weight.

(ii) Applicant argues that the claimed composition leaves a visible residue on the tooth is nowhere taught in the specification. Applicant's arguments filed have been fully considered but they are not persuasive. See reasons stated above. The rejection has below has been modified to address the amended claims submitted.

Claims 1-4, 8-11 remain rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Lawlor US 6,706,256 B2.

Lawlor discloses current claims 1, 4 and 6 hydrogenated starch (retentive agent) calcium carbonate (current claim 1) from 10-50 % at col. 21 lines 48-40, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, an anticalculus agent (col. 10 line 31) as in current claim 9, fluoride ions current claim 9 (see col. 11 line 48), the fluoride level is about 200-300 ppm (current claim 9) at col. 11 line 60, where the solid unit is a compressed tablet at col. 26 line 62 (current claim 10), water soluble buffers as sodium bicarbonate (see col. 21 line 62) as in instant claim 11. Lawlor also discloses the solubility as in current claims 2, 13 and 15 as 1g/100g at 25°C at col. 17 line 8 wherein the pH is from 3-10 at col. 22 line 5 + as in current claim 13. Claim 1 recites the solubility is less than 1g/30 g. As stated in the MPEP 2112.01 Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), it is also anticipated that the tablet will take at least five minutes in the oral cavity absent factual evidence because a composition as claimed in the instant claim 1, comprising all the claim limitations of the claimed invention will inherently possess the characteristics of the claimed composition, that is-non-effervescent and non-cariogenic. No patentability weight has been given to the duration of the time the composition is adhered to the teeth. The composition is visible on 2 or 3 molar or premolar surfaces to greater than 7 molar or premolar

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surfaces for 5 minutes to about 60 minutes – does not alter the compound nor the composition. Consequently, the reference anticipates the claimed invention defined in claims 1-4, 8-11.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor, US 6,706,256, and Blue, US 4,978,521 in view of Aberg et al., WO 88/10110 and Caldwell et al. US 5,622,980.

Lawlor discloses current claims 1, 4 and 6 hydrogenated starch (retentive agent) 10% at col. 20 line 66, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% (see col. 15 lines 9-10), where in the composition consist of an anticalculus agent (see col. 10 line 31) as in current claim 9, a fluoride ion current claims 10 (see col. 11 line 48), wherein the fluoride level is about 200-300 ppm (current claim 9), (see col. 11 line 60), where the solid unit is a compressed tablet at col. 26 line 62 (current claim 11). Lawlor also discloses the solubility as in current claim 2 1g/100g at 25°C (see col. 17 line 8). it is will be obvious that the tablet will take at least 5 minutes in the oral cavity absent factual evidence because a composition as claimed in the instant claim 1, comprising all the claim limitations of the claimed invention will inherently posses the characteristics of the claimed composition, that is-non-effervescent and non-cariogenic.

Blue teaches an oral care dentrifice composition comprising: as in current claim 1 as having 30-65% retentive agent -calcium carbonate at col. 1 lines 54-55, wherein the rententive agent is from 30-60% (taught in the reference as 30-65% which is within applicants' claimed range) an effective amount of surfactant referred by reference as detergent (see col. 1 lines 61-62) as in current claim 1, a buffer as in current claim 1 and 11 (see col. 1 line 56) as sodium bicarbonate, wherein the solid dosage form is a

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compressed tablet (see col. 3 lines 17-18) as in current claim 10, fluoride ion as in current claim 8 (see col. 2 line 53, see table).

The Blue reference teaches the solubility of the retentive agent –calcium carbonate to be less than about 1g/30g at 25°C, as in current claims 1 and 2. Blue also teaches fluoride ion as 1000 parts per million (col. 1 line 51) which is far greater than the claimed invention, however this can be substituted with that concentration of Lawlor to obtain the claimed invention because the Lawlor reference teaches the use of the concentrations of the claimed invention.

Blue, however, did not teach a non-effervescent solid dosage form per se.

Aberg et al., WO 88/10110 teach a non effervescent paste (page 5)

Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. The

Caldwell et al. teach, an oral composition comprising magnesium aluminium silicate (see abstract) as in the instant claims 6 and 7.

Although the Lawlor expressly did not teach a non-effervescent, non-cariogenic tablet, as discussed above in the reference, the composition comprising all of the limitations of the claimed invention will definitely have these properties.

Therefore one of ordinary skill in the art would have known to combine the teachings Lawlor with the teachings of the above cited reference to make and used the claimed invention at the time it was made because the invention is known to the ordinary skill in the art, how to make an oral dentrifice tablet that is non-effervescent,

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chewable, leave a substantial amount of the composition on the tooth surface because the active agent for a composition of a tooth tablet are well known within the art. One of ordinary skill in the art would know how to prepare a composition of this nature as the techniques are well known to the one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art and expect a successful result in doing so because the aim of preventive dentistry has been to improve the efficacy of oral hygiene in mammals. Next, having the composition on the teeth for 5 minutes will depend on the end user, if the user does not eat or drink anything for 5 minutes after the oral dentifrice is used, then the composition will be retained on the tooth surface for that length of period, if however the user drinks or eat immediately after use then the composition will not have any effect on the surface.

Although the Lawlor reference did not teach the specific retentive agent as magnesium aluminium silicate, one of ordinary skill in the art would have been motivated to substitute the calcium carbonate with that of magnesium aluminium silicate as taught by Caldwell et al. because the Lawlor reference teach addition of aluminas of silica gel precipitates. thedid not expressly teach magnesium aluminium silicate, it however teaches a syloid. Syloids are a trademark name and is inclusive of magnesium aluminium silicate.

With regards to the kit

The above rejection is applied to claim 12 and further explained below:

The printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container.

See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed

matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be

used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blue, US 4,978,521, Aberg et al., WO 88/10110 as applied to claims 1-12 above, and further in view of Lawlor, US 6,706,256 B2 and Witt, US 6,350,438 and Caldwell et al. US 5,622,980.

Blue teaches an oral care dentrifice composition comprising: as in current claim 1 as having 30-65% retentive agent-calcium carbonate at col. 1 lines 54-55, wherein the retentive agent is from 30-60% taught in the reference as 30-65% which is within applicants' claimed range (current claim 5) at col. 1 line 54-55, an effective amount of surfactant referred by reference as detergent at col. 1 lines 61-62 (current claim 1) a buffer as in current claim 1 and 11 at col. 1 line 56 as sodium bicarbonate, wherein the solid dosage form is a compressed tablet (current claim 10) at col. 3 lines 17-18, fluoride ion as in current claim 8 at col. 2 line 53 (see table), wherein the chewable composition has a retention index of from 1-about 4 as stated in the MPEP.

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Aberg et al., WO 88/10110 teach a non effervescent paste (page 5)

Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. ~~The~~

While the combined references above do not teach a method of use, Lawlor teaches a method of use-preventing halitosis (col. 6 line 15) as in current claim 13 wherein the pH range is from 3-10 as in current claim 13, at col. 22 lines 5+, calcium carbonate (current claims 13-14 and 16) from 10-50 % at col. 21 lines 48-40, wherein the buffer is sodium bicarbonate at col. 21 line 61 (current claims 13-14 and 16), surfactants at col. 18 lines 42+ as in current claims 13-14 and 16, chewable solid unit at col. 15 lines 46-47, non-cariogenic at col. 15 line 51 as in current claims 13-14 and 16, having flavor at col. 23 lines 12+, wherein the retentive agent has a water solubility of from 1g/30g or 1g/100 in current claims 13-17. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

Witt et al teach a method for treating diseases of oral cavity (abstract), having a pH of 7-12 at col. 4 lines 59-60. Although Witt did not use the concentrations of retentive agent as claimed by applicant, the reference teaches incorporating the agents claimed to make an oral care.

Therefore one of ordinary skill in the art would have combined the teachings of the cited prior art supra with that of Lawlor and Witt, make a compressed chewable tablet that when dissolved in the mouth gives a basic pH ranging from 7-12 because the

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prior art teaches the limitations of the claimed invention. It is obvious for the composition of oral care to stay within the oral cavity for 2 minutes, if the oral care is in the form of a lozenges or a slow dissolving tablet.

One of ordinary skill in the art would have been motivated to combine the teachings and expect a successful result in doing so as the agents of the claimed invention are well known to the one of ordinary skill in the art and would have implemented all and be successful in the treatment of the oral cavity.

With regards to the method of buffering the oral cavity, occurs naturally because once a composition of any kind enters the oral cavity, secretion of saliva is produced and the composition is automatically buffered.

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

Applicant's arguments have been fully considered but they are not persuasive. For the reasons discussed below:

Applicant traverses that:

The teachings of Lawlor would not have resulted in the claimed subject matter and that Aberg does not teach an oral dentifrice tablet that leaves a substantial amount of the composition on the tooth surface and is visible on the tooth surface.

These arguments are traversed, one of ordinary skill in the art would have been motivated to have the composition that is non-cariogenic and non-effervescent adhere to the 2 or 3 surfaces of the tooth because Lawlor gives the motivation to do so for patients with extremely bad halitosis (see col. 24, lines 39-48). Lawlor simply teaches

the present inventions are formulated to encourage the consumer to retain them in the oral cavity and the longer the better, even teaches that the composition can be reapplied from 1-10 times indicating that adhering to the tooth surface for a longer period is desired.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
12/5/06


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER